A comprehensive comparison between ISAC and ALEX multiplex test systems

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Background

Diagnosis of type I hypersensitivity is based on anamnesis, blood- and skin testing and provocation testing. Multiplex specific (sIgE) testing enables determination of sIgE antibodies against multiple recombinant or purified natural allergen components. The aim of this study was to evaluate the performance of the novel ALEX® (Allergy Explorer) multiplex platform and to compare it with the ImmunoCAP ISAC® test system.

Methods

Serum samples of 20 patients, routinely determined with ISAC, were selected based on positive results covering in total 101 of 112 ISAC components. Negative percent agreement (NPA) and positive percent agreement (PPA) of ALEX data compared to ISAC data (as a non-reference standard) were computed for common allergen components (n=80).

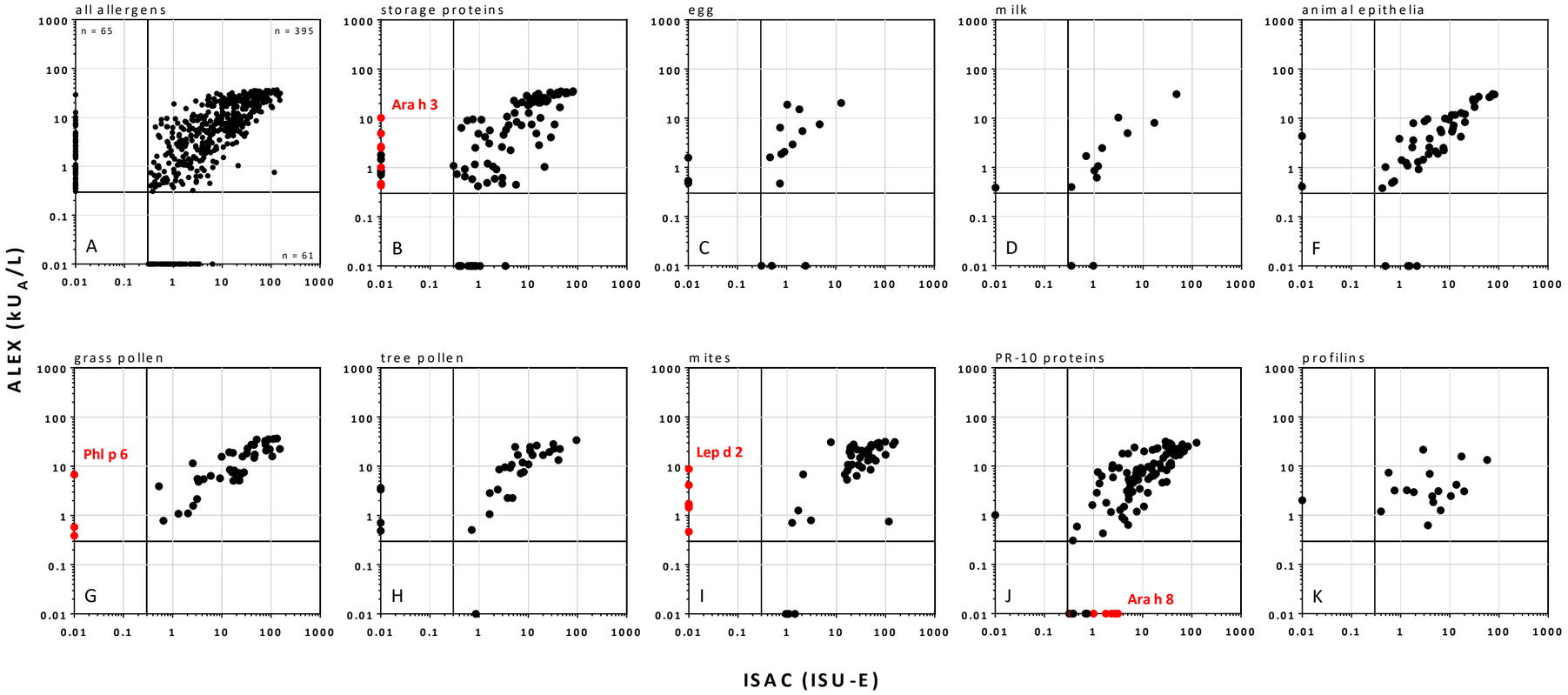

Figure 1. Scatter plots showing sIgE values measured with ISAC and ALEX multiplex test systems. Plot A, all allergens. Plot B-K, specific allergen groups.

Results

The overall agreement between ISAC and ALEX common allergen components was 92% (both negative (n=1079) + both positive (n=395)/1600*100%). The remaining results were ISAC+/ALEX- (n=61) or vice versa (n=65). Positive results for all allergens are plotted in figure 1A. Plot B-K show positive results for specific allergen groups. The NPA for a selection of food allergens (egg, milk, storage proteins), inhalation allergens (grass, tree, animals, mites) and cross-reacting allergens (LTP, PR-10, profilins) varied between 89%-98%. The PPA was high for inhalation allergens and profilins (91%-100%) and slightly lower for LTP, PR-10 and food allergens (68%-88%). Detailed analysis revealed that specific allergen components strongly influenced agreement values. Concerning NPA values, 6 of 6 ISAC-/ALEX+ mite allergen results were positive for Lep d 2 (plot I) and 3 of 3 ISAC-/ALEX+ grass allergen results were directed against Phl p 6 (plot G). Moreover, 6 of 13 ISAC-/ALEX+ storage proteins results were positive for Ara h 3 (plot B). Regarding PPA values, analysis of PR10 allergens showed that 7 of 12 ISAC+/ALEX- results were directed against Ara h 8 (plot J).

Conclusion

The comparison between ISAC and ALEX sIgE detection against common allergen components showed high overall agreement. Detailed analysis of NPA and PPA values revealed allergen specific differences between both test systems, possibly reflecting different allergen sources, concentrations and/or methods utilized to immobilize the molecules to different solid-phases.